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October 8, 2007

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Applicant: Trevor Honeyman et al.
Serial No.: 10/708,862
Filed: 03/29/2004
For: Fluid Delivery System
Our Reference No.: 1320.10

Art Unit: 3672
Examiner: Cloud K. Lee
Confirmation No.: 2861

Dear Sir:

Enclosed please find the following:

1. Certified United Kingdom Patent No. GB/0123340.2;
2. Certified United Kingdom Patent No. GB/0129813.2; and
3. Self-addressed and postage pre-paid post card to serve as a receipt for item 1-2.

Very respectfully,

SMITH & HOPEN

Ronald E. Smith

By: Ronald E. Smith
ron.smith@smithhopen.com
RES/lr
Encl.

CERTIFICATE OF MAILING
(37 C.F.R. 1.10)

I HEREBY CERTIFY that this correspondence is being deposited with the United States Postal Service as "Express Mail Post Office to Addressee," Mailing Label No. **EV896394811US**, addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on October 8, 2007.

Date: October 8, 2007

Lauren Reeves
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I, the undersigned, being an officer duly authorised in accordance with Section 74(1) and (4) of the Deregulation & Contracting Out Act 1994, to sign and issue certificates on behalf of the Comptroller-General, hereby certify that annexed hereto is a true copy of the documents as originally filed in connection with patent application GB0123340.2 filed on 28 September 2001.

n accordance with the Patents (Companies Re-registration) Rules 1982, if a company named this certificate and any accompanying documents has re-registered under the Companies ct 1980 with the same name as that with which it was registered immediately before re- gistration save for the substitution as, or inclusion as, the last part of the name of the words ublic limited company" or their equivalents in Welsh, references to the name of the npany in this certificate and any accompanying documents shall be treated as references to name with which it is so re-registered.

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Dated 19 September 2007

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28SEP01 E663391-1 D02346
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Request for grant of a patent

(See the notes on the back of this form. You can also get an explanatory leaflet from the Patent Office to help you fill in this form)

1. Your reference — **JCD/MK/8626-GB**

2. Patent application number *(The Patent Office will fill in this part)* — **0123340.2** — 28 SEP 2001

3. Full name, address and postcode of the or of each applicant *(underline all surnames)* — **Honeyman Water Limited**
Harmire Enterprise Park
Barnard Castle
County Durham
DL12 8BN

Patents ADP number *(if you know it)* — 8218265001

If the applicant is a corporate body, give the country/state of its incorporation — **England**

4. Title of the invention — **Fluid Delivery System**

5. Name of your agent *(if you have one)* — **Bailey Walsh & Co.**

"Address for service" in the United Kingdom to which all correspondence should be sent *(including the postcode)* — **5, York Place**
Leeds
LS1 2SD

Patents ADP number *(if you know it)* — **224001**

6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and *(if you know it)* the or each application number

Country	Priority application number *(if you know it)*	Date of filing *(day / month / year)*

7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application

Number of earlier application	Date of filing *(day / month / year)*

8. Is a statement of inventorship and of right to grant of a patent required in support of this request? *(Answer "Yes" if:* — **Yes**

a) *any applicant named in part 3 is not an inventor, or*
b) *there is an inventor who is not named as an applicant, or*
c) *any named applicant is a corporate body*
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Request for preliminary examination and search *(Patents Form 9/77)*	
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Any other documents *(Please specify)*	

11. I/We request the grant of a patent on the basis of this application

Signature

Date

28th September 2001

12. Name and daytime telephone number of person to contact in the United Kingdom

J C DENMARK
0113 2433824

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Fluid Delivery System

This invention relates to a fluid delivery system, and more particularly to a hygienic fluid delivery system, the construction of which requires careful planning and analysis to ensure that the resulting system has minimal stagnancy of flow during operation and that bacteria growth is minimised if not eliminated entirely.

Although the following description is provided with almost exclusive reference to hygienic fluid delivery systems which deliver so-called Water for Injection (WFI), Purified Water (PF) and the like, it will be instantly appreciated that the invention has far wider application and may be applied to deliver any liquid to a predetermined location remote from a storage vessel through distribution pipework. Typical installation sites include premises for the pharmaceutical, healthcare and medical device industries.

It is also to be appreciated by the reader the word "sterile" and cognate expressions as used hereinafter is not to be construed in its literal sense and includes liquids having a bacteria, germ or other contaminant content reduced beneath a desired level to that the said liquids are safe or suitable for a particular procedure.

Current systems for the delivery of sterile fluids, in their simplest form, consist essentially of a storage vessel supplied intermittently or continuously with a sufficient volume of pre-sterilised .fluid A system of steel pipework is routed through the premises, for example a clinical laboratory, wherein WFI is required, said pipework being for the most part conventionally concealed in the ceiling of each room through which said pipework passes and descending from the ceiling only in those

locations either where operatives are likely to regularly require a source of WFI or alternatively in locations conveniently accessible by a number of operatives working proximate said location. The pipework is routed through said premises and ultimately returns to the storage vessel to return any excess fluid thereto.

There are a number of important factors which must be taken into account when designing a sterile fluid delivery system, but the most important is that the system as a whole must generally preclude any localised stagnation of fluid, either in the pipework or the storage vessel and be free from crevices or similar areas where bacteria could become trapped and thus allowed to proliferate

Accordingly the pipes are firstly commonly welded together using a very costly technique known as Tungsten Inert Gas (TIG) autogenous welding which ensures that the butt joints between adjacent sections of pipe are secured to one another without introducing unwanted contaminants into the passageway within the pipes and ensuring that the join is as smooth as possible internally. Furthermore the interior surface of the various pipes which are joined together throughout the system is important in that said interior surface must be as smooth as possible and any bends in the pipes must preclude the formation of eddy currents during fluid flow therethrough. It will be appreciated that eddy currents give rise to localised volumes of fluid which are effectively stationary, and thus the temperature of these volumes can quickly drop to a level at which bacteria most readily thrive with the result that the sterility of the system as a whole is prejudiced.

Secondly, the operating temperature of the system is adjusted and maintained to ensure that any bacteria (for example

mesophilic bacteria such as gram-negative pseudomonas commonly present in water) are either prevented from multiplying or are actually eliminated. A common temperature for WFI systems is 80°C and to prevent any gradual reduction of the fluid temperature over time, a heater is commonly connected into the system.

It is to be mentioned that PW and other hygienic fluid systems can be operated at ambient temperatures, so much greater care and attention needs to be given to the construction of these types of systems which on account of the operating temperature are much more prone to bacterial proliferation.

Thirdly, it is important that a turbulent, as opposed to a laminar flow characteristic is developed within all sections of the pipework again to minimise the risk of bacteria proliferation. For example, in both laminar and turbulent fluid flows, it is well known that the velocity of the fluid immediately adjacent a solid surface is minimal if not zero, whereas the velocity of fluid remote from such a surface is much greater. Hence the majority of the volumetric flow through a pipe is achieve through the middle of the pipe whereas only a comparatively small percentage of flow is attributable to the fluid moving proximate the interior surfaces of said pipe. This slow moving or stagnant fluid has the tendency to cool and thus not only are the conditions for bacteria proliferation improved adjacent to the interior surface of the pipe, but the fact that the fluid is either moving very slowly or not at all further increase the likelihood that bacteria will find a site on the pipe surface to germinate.

Turbulent fluid flows within sterile fluid delivery systems are desirable because velocity profile of the fluid proximate the interior surface of the pipe increase significantly more sharply than that of an equivalent laminar flow and the risk of bacteria

proliferation and germination is thus mitigated. Biofilm formation on the internal surfaces is discouraged by such fluid velocities.

However, it is well known in fluid dynamics that the existence of turbulent flows within pipes depends on, among other things, the diameter of the pipe, and the velocity of fluid flow therethrough. In general, to the development of turbulent flow in pipes of a larger diameter requires a significantly larger fluid velocity than required to establish turbulent flow in smaller diameter pipes.

Fourthly, it is necessary to ensure that the storage vessel containing the WFI is recharged over a predetermined period of time, for example every two hours. Moreover, the system operates continuously so that the storage vessel is being continually emptied and simultaneously recharged to avoid any stagnation of fluid therein, and the time period is merely an indication of the length of time which would be taken to empty to the storage vessel completely under normal operating conditions without any simultaneous recharge.

It will also be appreciated that the systems with which this invention are concerned may have many tens of outlets or so-called offtakes as an entire laboratory or building may need to be served by a single fluid delivery system. The diameter of the pipes commonly used in such systems may be of the order of 1-2½ inches (25-64mm), and to ensure a turbulent flow within such a pipe the flow velocities are typically between 1-3m/s.

In order to develop such a flow velocity, substantial and thus costly pumping apparatus is required, and when it is also considered that a number of different offtakes may be in use simultaneously, dynamic control of this pump and/or

alternatively some means of pressure regulation is required. Conventional Fluid delivery systems must possess an ability to deliver fluid through a number of off-takes opened simultaneously while nevertheless operating satisfactorily when none of the offtakes are in use, for example overnight. The inherent disadvantage of series-type systems, in which a plurality of offtakes are connected in series such as described, is that the opening of more than a few offtakes simultaneously can have detrimental effect both on the flow characteristics and the ability to draw water at the correct flow and pressure at the various user offtakes. The number of offtakes which can be opened simultaneously in a system expressed as a percentage of the total number of offtakes in a system is known as the diversity.

Various different pipework loop and sub-loop configurations having different benefits and effects on diversity have been proposed.

Referring now to Figures 1, 2, 3, and 4 which show different fluid delivery systems of prior art configuration, each of these systems shows a storage vessel 2 with which pipework 4 communicates to both feed offtakes 6 which are embodied most simply in an openable valve and to return excess fluid to the storage vessel at 8.

Each of the systems shown in the Figures comprises at least one pump 10 and in the case of Figure 2 a second pump 12, each of which urges fluid through the pipework around the system in a flow direction 14.

It can be seen from Figure 1 that the pipework is sloped at 16 between off takes and this is a common feature of such systems to allow for drainage of the fluid from the system for cleaning

purposes. A heater 18 and a pressure regulating valve are also provided in series with the various offtakes 6 and it will be appreciated that this simple series system functions in a very similar manner to a simple series electrical circuit, with the pump corresponding to a source of potential difference, the offtakes corresponding to resistances dissipating power and the flow rate corresponding to the current. Indeed the analogy can be extended in the cases of Figures 2, 3, and 4 which effectively show parallel circuits.

The importance of this analogy is that as further offtakes are added into a particular loop, the fluid flow which the system is capable of delivering through each of the offtakes when open is reduced depending on the number of offtakes in that loop. This is identical to the reduction in brightness of lightbulbs connected in series in an electrical circuit as more and more lightbulbs are connected.

In the case of Figure 2 which shows a multiple loop arrangement, a second pump 12 drives fluid through a second loop of the system and effectively provides sufficient flow through said loop to feed the various offtakes in that loop. In the case of Figure 3, a sub-loop or true parallel arrangement is shown, and in the case of Figure 4 a more complex main loop/sub loop arrangement is shown wherein four separate sub loops 22, 24, 26, 28 are fed from a main loop 30. Each of the sub loops is provided with a diaphragm valve 32 immediately after the join to the main loop, and additionally Constaflo™ flow regulating valves are provided on each of the sub loops, at the most remote end of the main loop, and on a return loop 36 which links the main loop immediately after the pump 10 to the storage vessel 2. Without unnecessary description and analysis of the working of this arrangement, the diaphragm valves, flow regulating valves and return loop are all provided with a view to

increasing the effective diversity of the system as a whole and to ensure correct hydraulic balancing of the system.

The fundamental disadvantages of the systems described other than their limited ability to operate at maximum diversity are primarily related to the perceived permanent nature of the construction. For instance, in order to deliver a sufficient quantity of fluid around the system, the pipes must be of large diameter which both increases the cost of materials and construction. Stainless steel pipe sections currently used in the construction of such systems typically are provided in only 6m lengths which necessitates a considerable amount of welding and increases the risk of areas of bacterial germination around the system due to crevices introduced through such welding or alternative jointing procedures.

In the event that an additional offtake is required in already installed system, it is very difficult and/or costly to modify the system, but perhaps most importantly the disruption to the system caused by modification can be severe. For example, the insertion of an additional offtake would necessitate a full draining of the system, opening the system to insert the additional pipework and offtake required, together with subsequent resterilisation and re-charging. Furthermore, the additional offtake could foreseeably necessitate a larger pump and additional flow and pressure regulating components. It has been estimated that the average cost of installation of a fluid delivery system is approximately £200 per metre and it will thus be appreciated that these systems can significantly increase the cost of premises construction. The welding process is also subject to rigorous and costly inspection and qualification procedures as part of the regulatory traceability requirements of HM Medicines Inspectorate and the like.

It is an object of this invention to provide a fluid delivery system whose effective diversity is above 90% and preferably approximately 100% but which is significantly less expensive than prior art systems to construct , install, and qualify..

It is a further object of the invention to provide a system which can be installed with the minimum number of crevices and imperfections in the interior surface of the pipework through which the fluid flows, and additionally to offer the possibility of installing a substantially crevice-free system, at least in the pipework coupling the offtakes to the pumping room. It is a further object of the invention to provide a system with as few joints between respective sections of pipework as possible.

According to the invention there is provided a fluid delivery system comprising a storage vessel for fluid which feeds a first pipework loop including a first pump which urges fluid through said first loop at a first pressure which ultimately returns to said vessel, said storage vessel also feeding a pipework branch including a second pump which urges fluid through said branch at a second pressure, characterised in that each of said first loop and said branch are provided with loop and branch manifolds having at least a fluid inlet and one or more fluid outlets, said manifolds being disposed downstream of said first and second pumps, fluid communication between said manifolds being achieved by at least one hose connectable to fluid outlets on respective manifolds and including an offtake thus allowing fluid flow from the storage vessel through the pipework branch, branch manifold, hose, loop manifold and pipework loop ultimately returning to said storage vessel and permitting fluid offtake at a desired location.

Preferably, said loop manifold is provided with a fluid inlet and a primary fluid outlet to allow for connection of said manifold

within said loop and a plurality of secondary outlets to which hoses having offtakes may be connected to allow for fluid communication with the branch manifold.

Further preferably the branch manifold is provided with a fluid inlet and only secondary outlets to which hoses having offtakes may be connected such that the fluid flowing into said branch manifold is urged into one or more hoses.

Preferably the fluid pressure within the loop manifold is greater than the fluid pressure in the branch manifold, and most preferably both these pressures are above ambient atmospheric pressure such that the opening of an offtake opens the fluid within to atmospheric pressure and the fluid flow direction in the length of hose between said offtake and said loop manifold reverses and both manifolds urge fluid towards said open offtake.

Preferably each hose is provided with only a single offtake, and further preferably each hose is made of a flexible polymeric or plastics material such as PTFE.

Preferably, the hose diameter is in the region of 5-25mm.

Most preferably at least one of the first or second pumps is dynamically controlled depending on the fluid pressure within the respective loop or branch manifold, and most preferably the pump driving fluid through the loop is dynamically controlled.

Most preferably only the second pump is dynamically controlled depending on the fluid pressure within the respective loop and branch manifolds.

The system described above has the surprising advantage that the opening of any offtake provided on any particular hose connection between the manifolds causes a reversal in the direction of fluid flow in the hose section from the loop manifold to the said offtake. Such flow direction reversal is achieved because the fluid pressure developed in the loop manifold is greater than the pressure developed in the branch manifold and thus the fluid is urged through the offtake (which is effectively at atmospheric pressure once opened) along both sections of hose linking the offtake to said manifolds.

The system has many attendant advantages resulting from the novel arrangement described, particularly including

1. lower cost of installation and associated validation
2. elimination of need for site-wide welding and the associated hazards of this process;
3. facility for installation by non-specialist contractors (as the hoses and offtakes may be installed by for example electrical cable installers);
4. easy relocation/isolation of individual offtakes;
5. future pre-cleaned offtakes can be easily added to the spare manifold secondary outlets and brought on-line without interruption to the live existing system;
6. offtake hoses can be individually sterilised;
7. hoses can be drained by (sterile) air or gas being blown therethrough thus avoiding extra costs for routing gravity drainage, and
8. hose sterilisation can be achieved by a number of methods, such as chemical recirculation, steam out, hot sterile air (160°C), ozone.

Perhaps the most important advantage is that provided the pumps are effectively dynamically controlled, the diversity of the system remains at almost 100% as more and more offtakes are

simultaneously opened. The only limit to the number of offtakes which can be opened simultaneously without any appreciable flow reduction therethrough is the diameter of the pipes and manifolds through which the fluid is urged by the pump (and thus the volume of fluid which can be delivered to the manifolds by said pumps).

A specific embodiment of the invention is now described by way of example with reference to the accompanying drawings wherein

Figures 1-4 schematically show fluid delivery systems of prior art configuration,

Figure 5 schematically shows a fluid delivery systems according to the invention,

Figures 6, 7 show details of possible offtake shroud assemblies,

Figures 8, 9 show perspective views of possible loop and branch manifold assemblies, and

Figures 10, 11 show schematically possible offtake assemblies.

Referring firstly to Figure 5 there is shown a fluid delivery system 50 comprising a storage vessel feeding pipework 52 which divides into a pipework loop 54 and a pipework branch 56. The loop 54 ultimately returns to the storage vessel 52 at 58 to recharge said vessel with fluid pump around the system.

In each of the loop 54 and the branch 56 are provided pumps 60, 62 respectively which are located upstream of a loop manifold 64 and a branch manifold 66 each of which has at least a primary fluid inlet 64A, 66A and a number of secondary fluid

outlets 64B, 66B to which hoses 64C, 66C can be connected. Each of the hoses 64C, 66C is connected to an offtake which essentially comprises an openable valve which when closed allows fluid by pass from the hoses 66C to 64C.

In a preferred embodiment, the pumps 60, 62 are dynamically controlled by coupling the pump motor to manifold pressure sensors schematically represented at 70, 72 in response to changes in fluid pressure inside the manifolds 64, 66. In this manner, the fluid flow and pressure can be automatically maintained at required levels when one or more of the offtakes is opened to deliver fluid therethrough. It is to be mentioned that this arrangement provides the most accurate control, but once the operating limits of a particular system are determined it is more likely that only a single pump need be dynamically controlled.

Downstream of the loop manifold, there may optionally be provided a sanitisation unit and/or a heat exchanger 73, 74 to ensure that the desired temperature is maintained during operation. Thereafter fluid is returned to the vessel 52 from which it is later pumped around the system.

Example system operating conditions include a minimum flow rate of 100litres/min in the pipework branch, a maximum flow rate of 160litres/min, a pressure of 6bar in the branch manifold, and a minimum flow rate of 45litres/min in the pipework loop, a maximum flow rate of 225litres/min and a loop manifold pressure of 2 bar.

Figure 5 also schematically shows a possible layout of the system in that the the bulk of the apparatus used in the system is located in a plant room schematically defined above the dotted line 76, a portion of the length of the hoses 64C, 66C which

communicate with the offtakes and the respective loop and branch manifolds are disposed in a roof or wall void represented between dotted line 76 and a further ditted line 78, and the offtakes 68 are optionally connected at the end of shrouds secured to the roof or walls to conceal the hoses.

Examples of such shrouds 80, 82 and offtakes 84, 86 are shown in Figures 6 and 7.

Figures 8, 9 show possible embodiments of the loop manifold 64 and branch manifold 66. The manifolds are different because fluid is required to flow through the loop manifold 64 from a primary inlet 64A to a primary outlet 64A' in the direction indicated at 88. There are further provided various secondary fluid outlets 64B the number of which corresponds to the number of offtakes desired in a particular system, and although the word "outlet" is used in connection with these fittings, it is to be appreciated that fluid in generally will only flow out of same when the particular offtake fed by the hose connected to said outlet is opened. In the alternate circumstance when the offtake is closed, fluid will flow into the manifold through outlet and be combined with the fluid flow through the manifold from one end to the other as indicated at 88. A pressure control outlet PC for dynamic pump control and a spare instrument access 90 are also provided.

In the case of the branch manifold 66, a primary inlet 66A is provided, together with a number of secondary outlets 66B to which the hoses 66C are connected. A pressure control outlet PC is disposed at one end of the manifold 66 whereas the opposite end is blanked off at 92 to prevent any fluid escape through said end. In the case of the branch manifold, fluid flows continually through the outlets 66B regardless of whether the offtakes fed by hoses 66C are open or closed.

Finally referring to Figures 10 and 11, there is shown a schematic representation of an offtake having connectors 94, 96 to which hoses 66C, 64C are connected to feed the offtake with fluid. A chamber 98 is provided which allows for fluid flow from hose 66C to hose 64C when the offtake is closed and for fluid reversal in hose 64C when the offtake is opened, and this in turn is connected to a standard diaphragm valve or similar 100 having actuator 102 if necessary.

A schematic sectional view of the chamber is shown in Figure 11 and it can be seen from this figure that the flow of fluid within said component may be achieved by orifice plates 104 provided internally thereof.

In circumstances where a user only gradually opens a valve to an offtake, it is foreseeable, depending on the design of the various components within a system, that the fluid flow velocity within hose 64C could merely reduce as opposed to become reversed, and in particular circumstances it may also transpire that on opening an offtake by a predetermined amount, the fluid velocity in the hose 64C reduces to zero, said offtake being supplied entirely by fluid flow to the offtake through hose 66C. Such operating conditions are envisaged only transiently and would not prevail for any significant length of time which could materially affect the hygiene of the fluid within the system as a whole. It is also to be mentioned that these particular operating characteristics will only arise infrequently, and the most desirable system operation will involve the reversal of fluid flow direction through hose 64C.

TYPICAL (BASIC) LOOP ARRANGEMENT INDICATING SLOPES AND OFFTAKE DETAIL

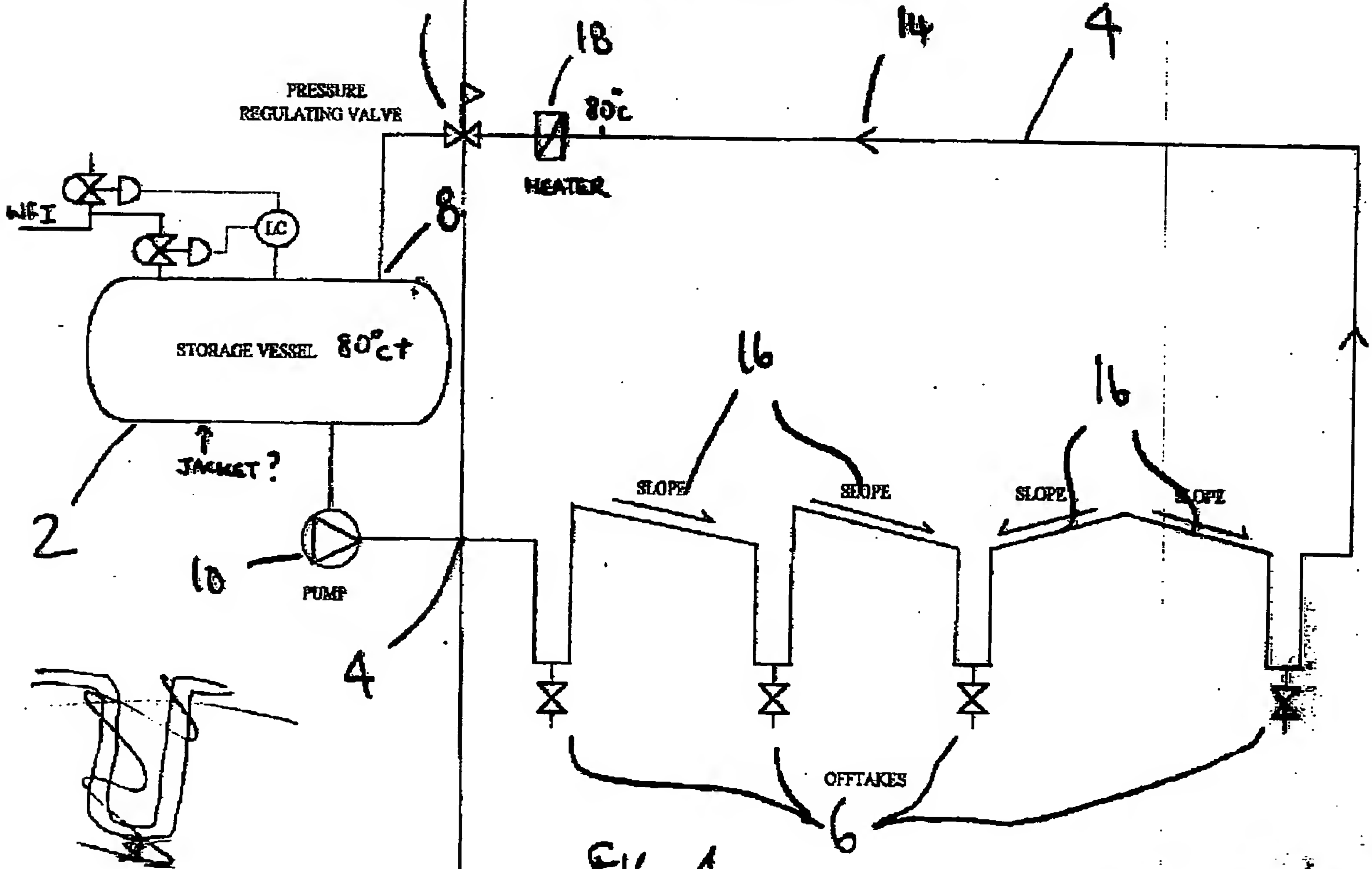

FIG. 1.

MULTIPLE LOOP ARRANGEMENT

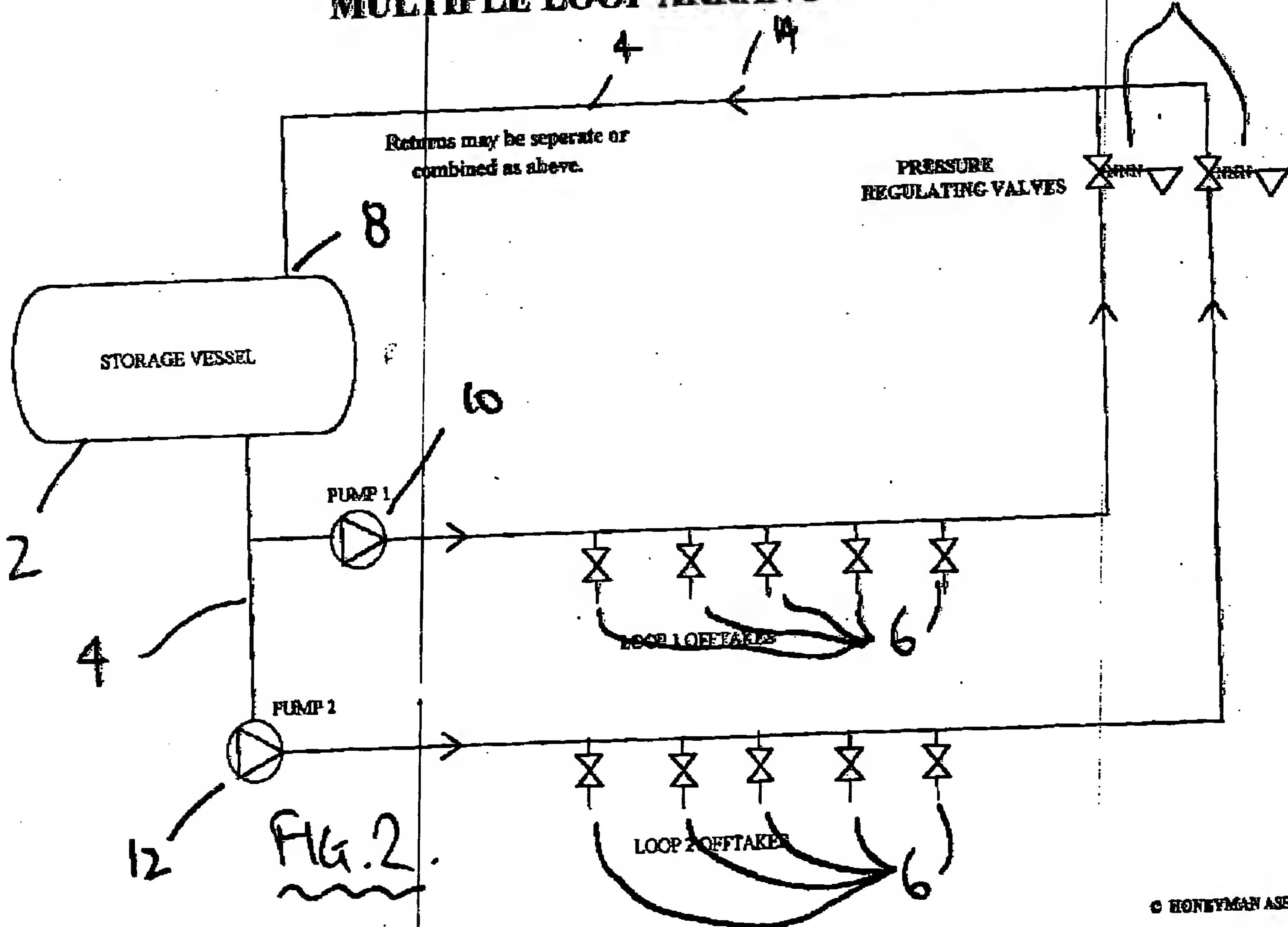

FIG. 2.

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SUB-LOOP ARRANGEMENT

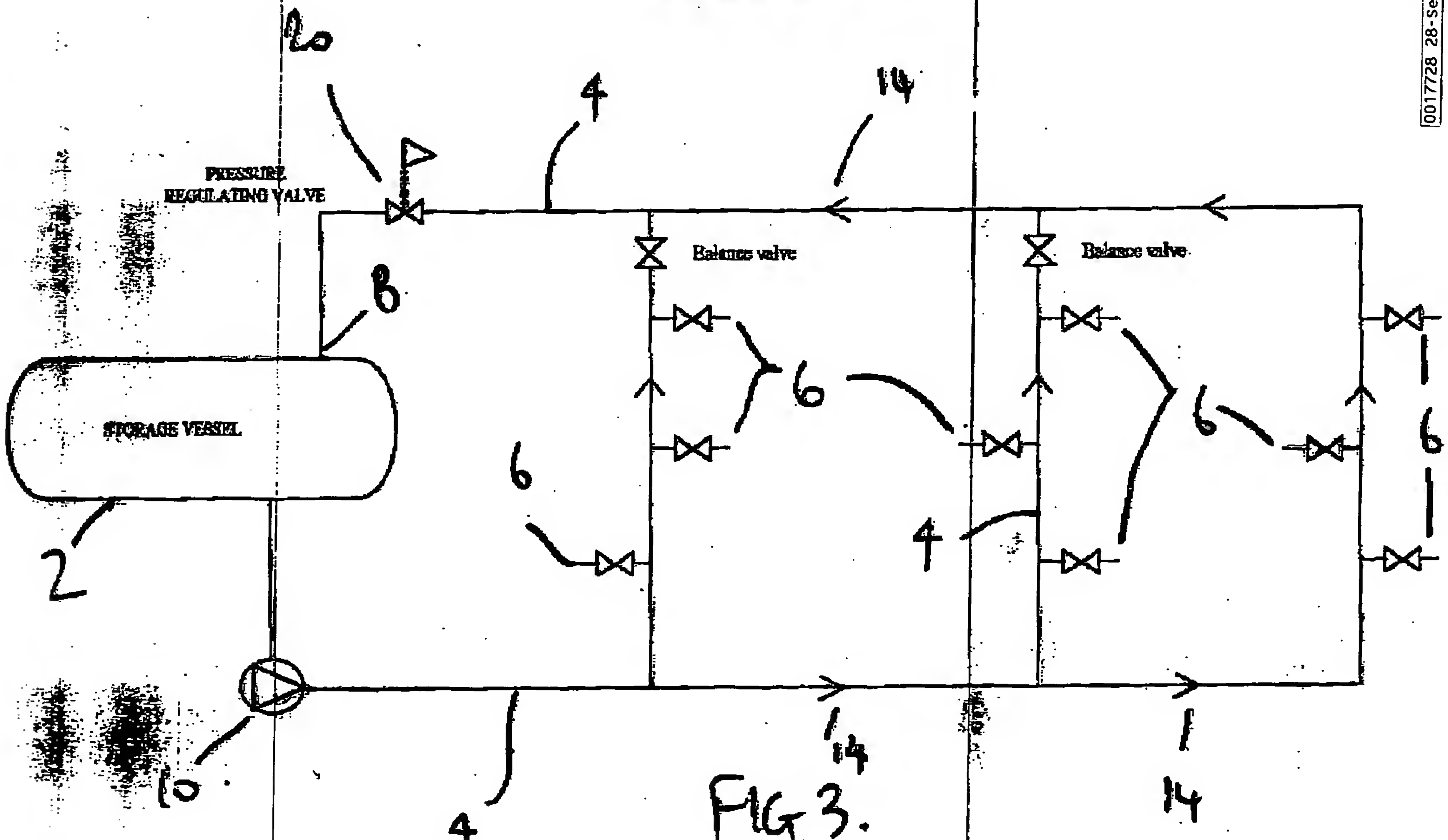

FIG. 3.

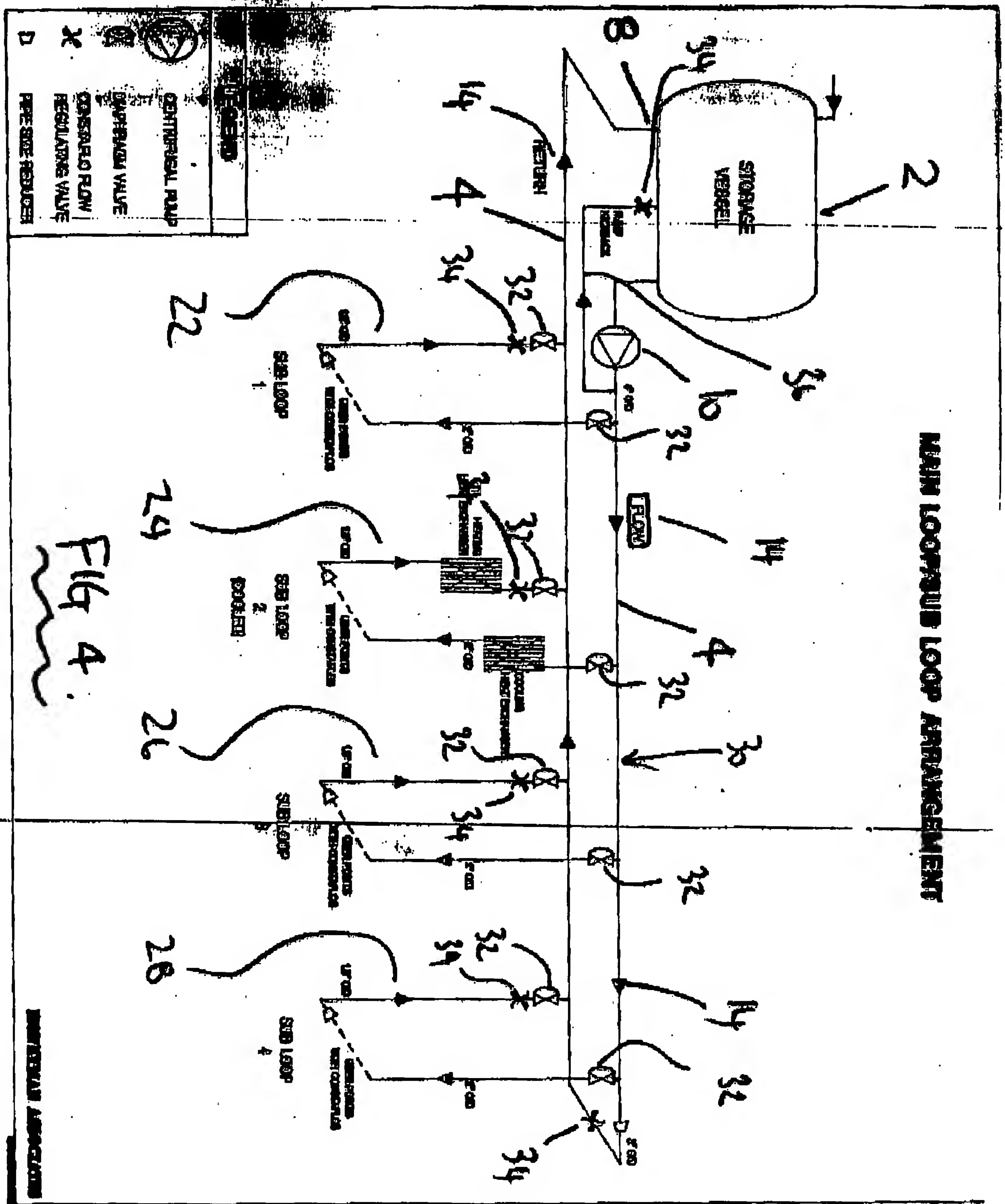
MAIN LOOP/SUB LOOP ARRANGEMENT
STORAGE VESSEL
FLOW
RETURN
LEGEND
CENTRIFUGAL PUMP
DIAPHRAGM VALVE
CONSTAFLO FLOW REGULATING VALVE
PIPE SIZE REDUCER
SUB LOOP 1
SUB LOOP 2
SUB LOOP 4
2
4
8
10
14
22
24
26
28
30
32
34

FIG 4.

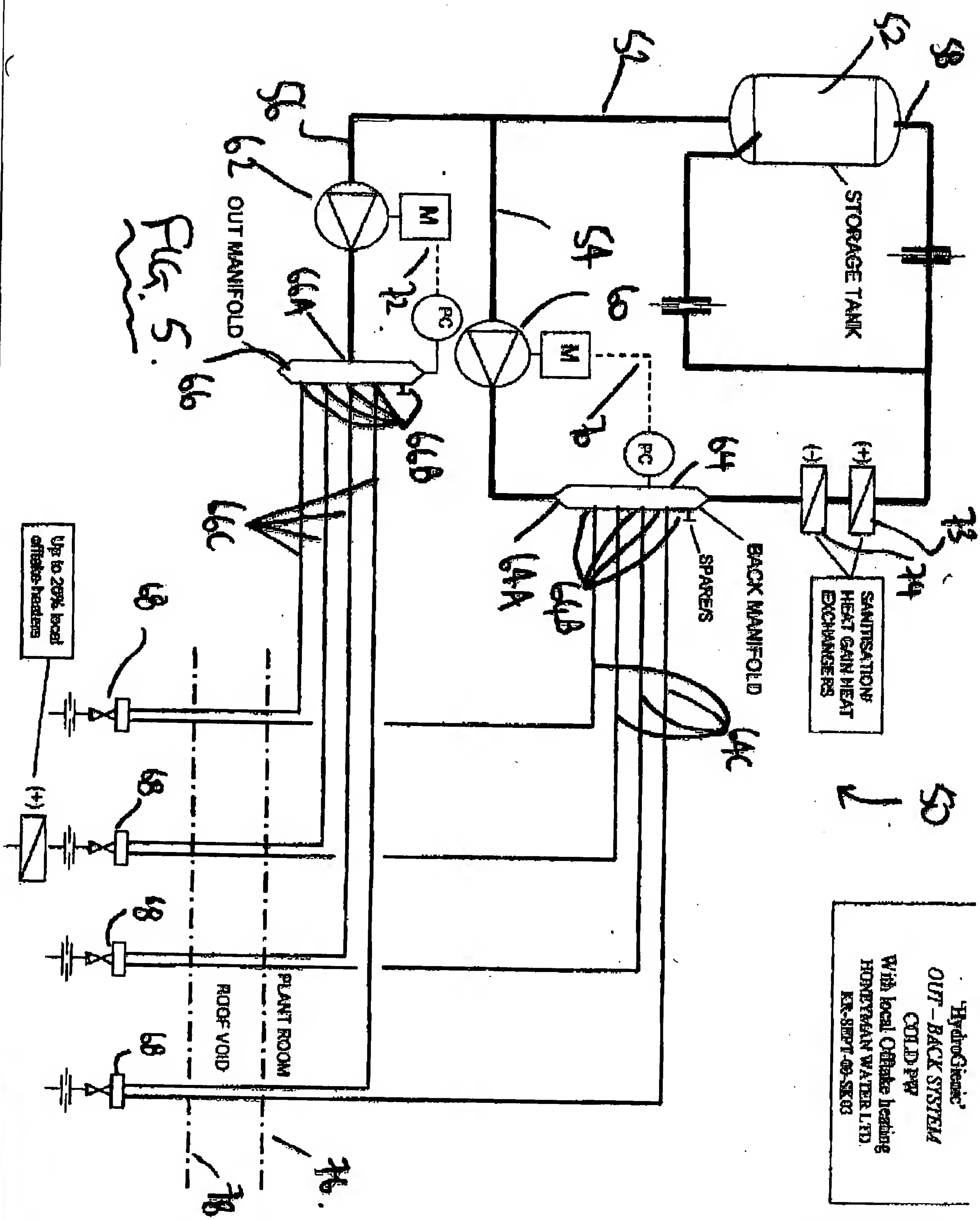
STORAGE TANK
M
PC
OUT MANIFOLD
BACK MANIFOLD
SPARES
SANITISATION/ HEAT GAIN HEAT EXCHANGERS
(+)
(-)
Up to 20% local offtake heaters
PLANT ROOM
ROOF VOID
"HydroGienic"
OUT–BACK SYSTEM
With local Offtake heating
HONEYMAN WATER LTD.
50
52
54
56
58
60
62
64
64A
64B
64C
66
66A
66B
66C
68
72
73
74
76
78

FIG. 5.

OFFTAKE SHROUDS

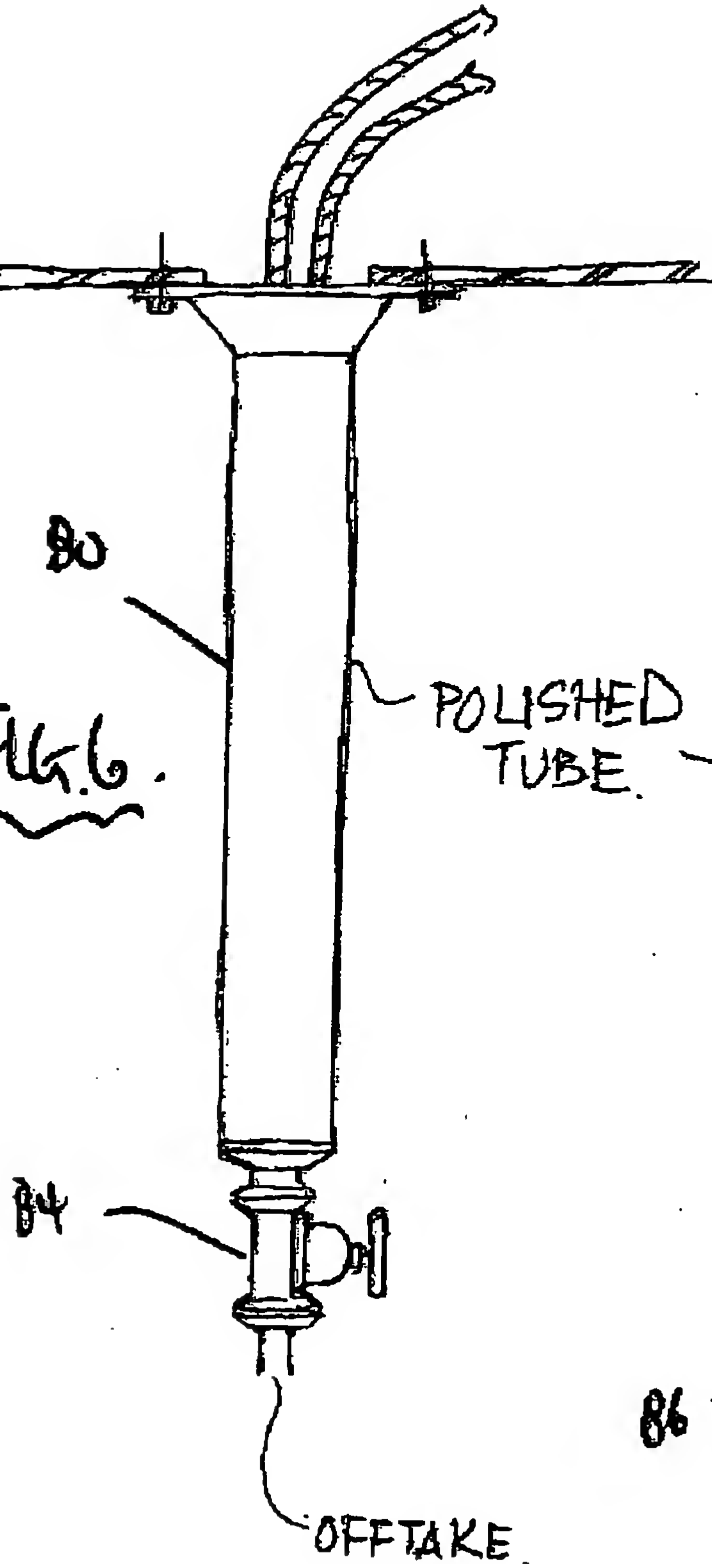

FIG.6.

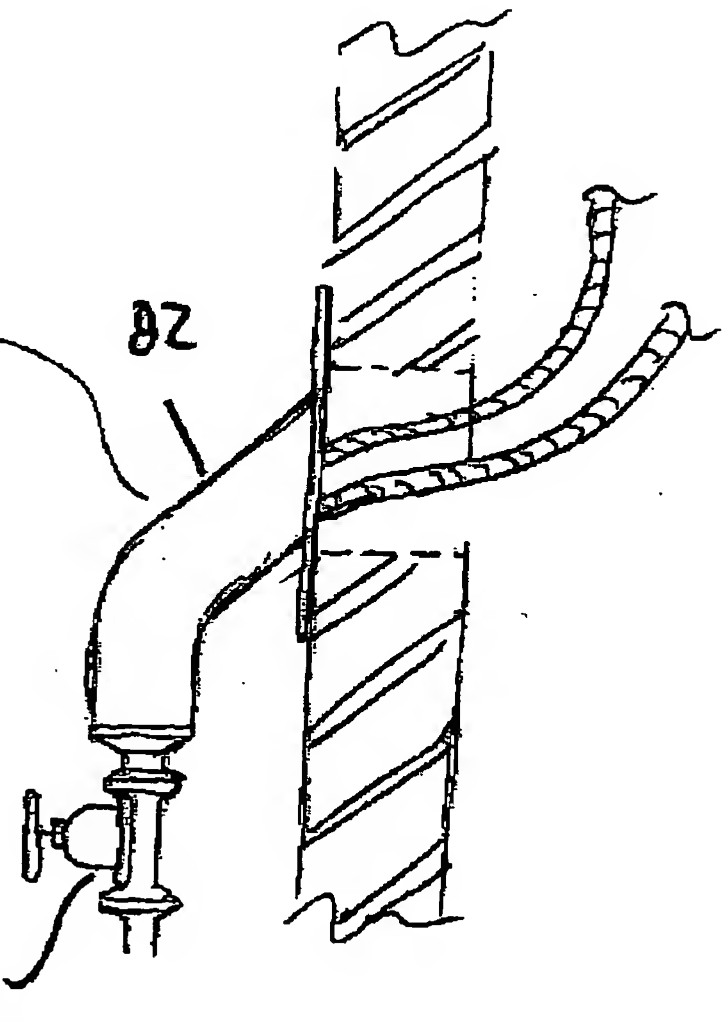

FIG.7.

MANIFOLDS

(MADE FROM ST.ST.
O/D TUBE & FITTINGS)

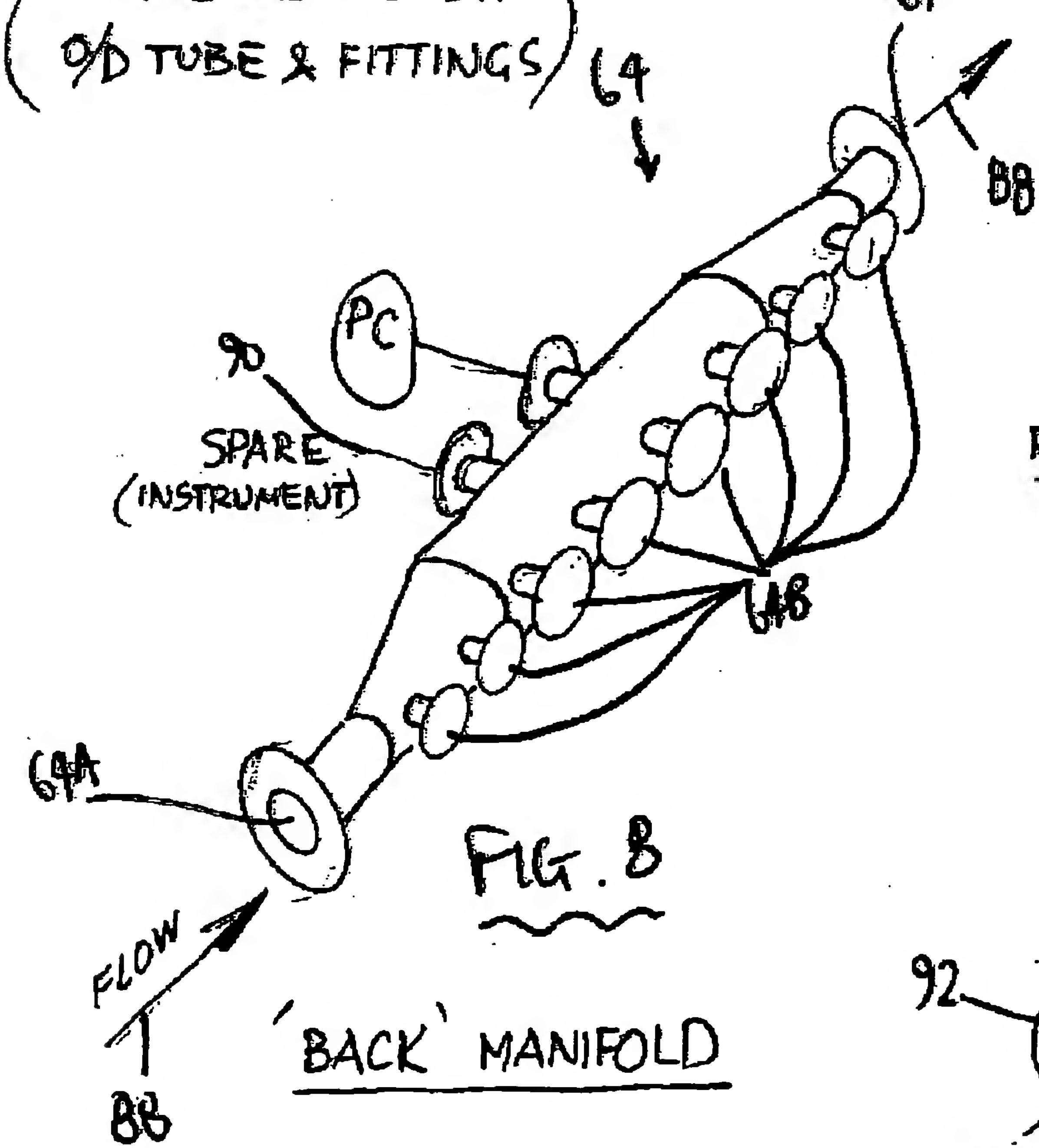

FIG. 8

'BACK' MANIFOLD

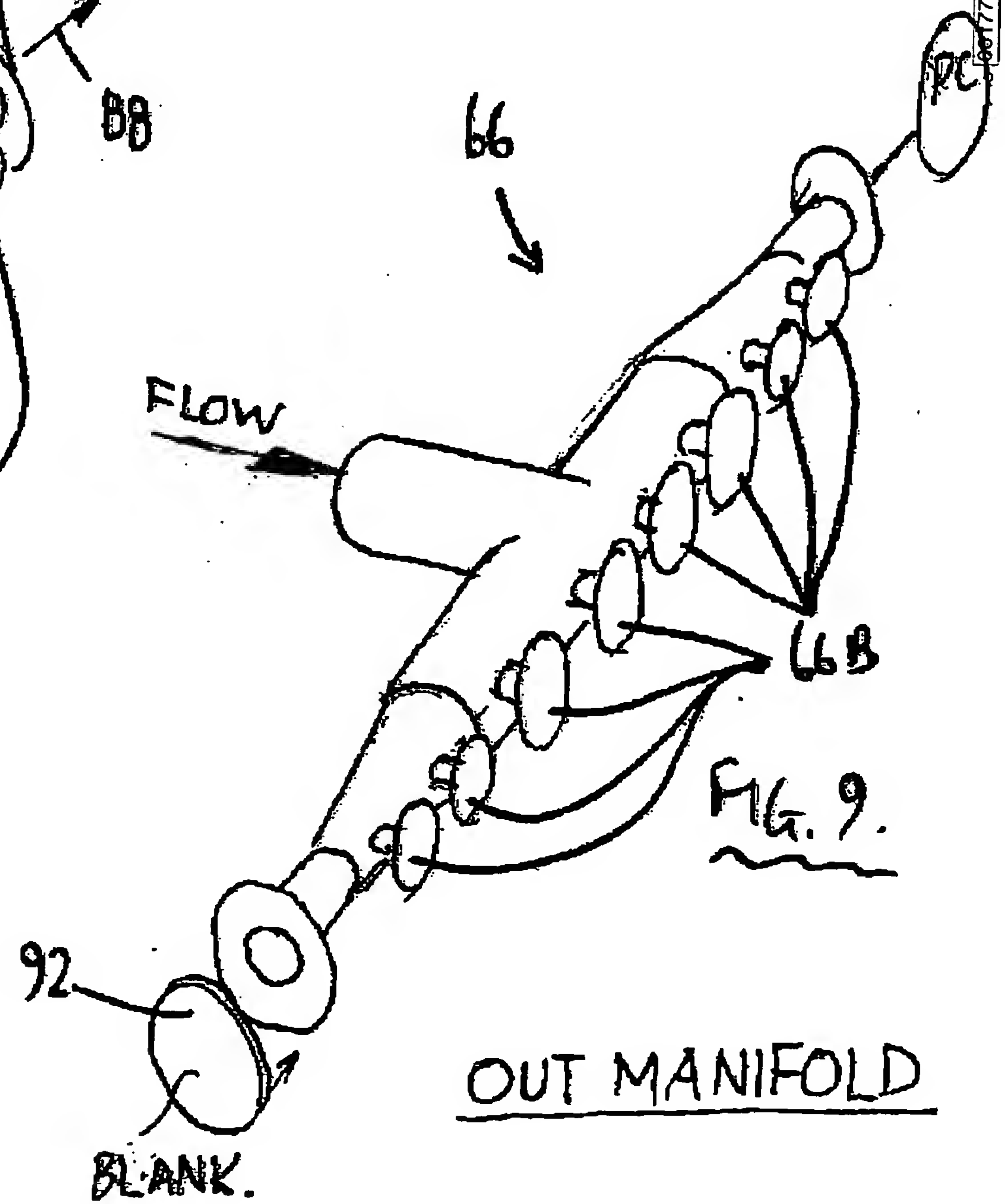

FIG. 9.

OUT MANIFOLD

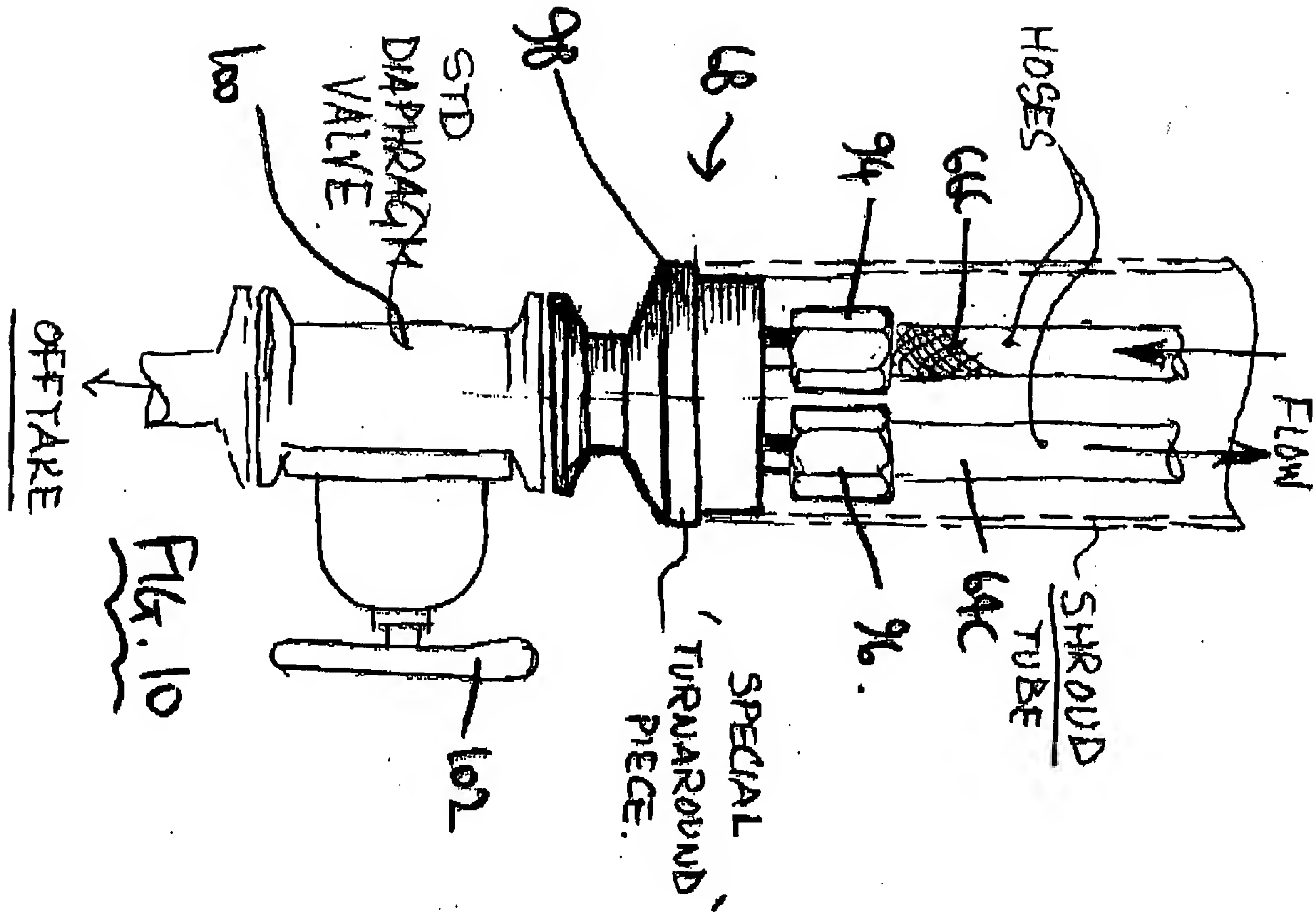
HOSES
FLOW
SHROUD TUBE
94
64C
96
68
98
SPECIAL 'TURNAROUND' PIECE.
STD DIAPHRAGM VALVE
100
102
OFFTAKE

FIG. 10

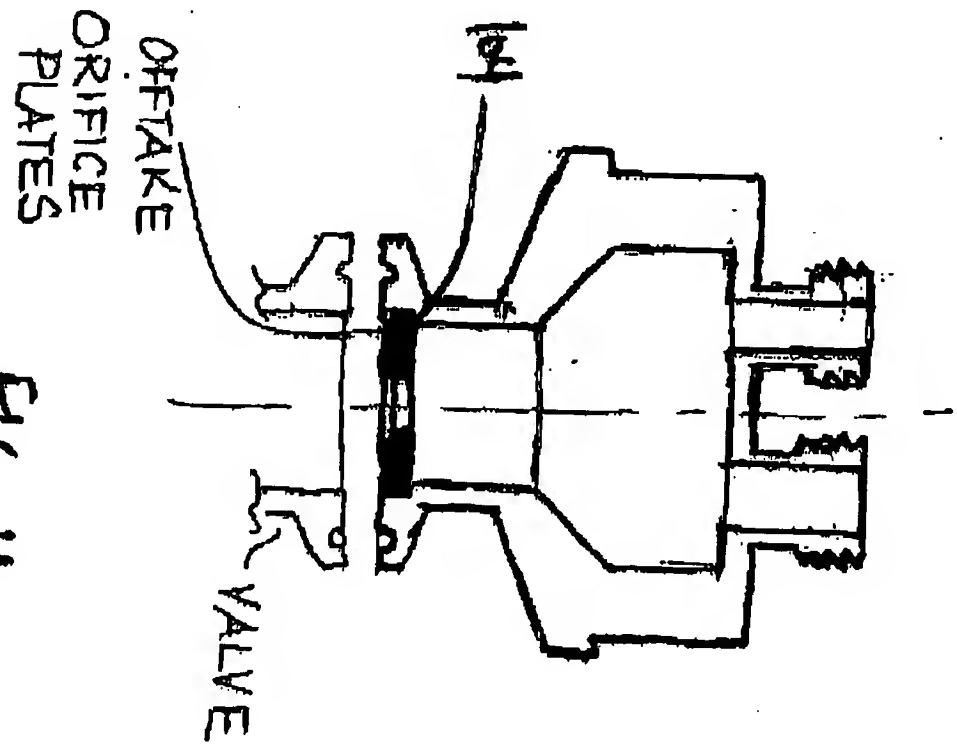
104
OFFTAKE ORIFICE PLATES
VALVE

FIG. 11